OLR Bill Analysis

sHB 5262

AN ACT CONCERNING THE PHARMACY PRACTICE ACT AND COUNTERFEIT DRUGS.

SUMMARY:

This bill makes several changes to the pharmacy laws, including adding requirements for (1) sterile compounding, including making certain compounding pharmacies register as drug manufacturers; (2) counterfeit substances; (3) nonresident pharmacies; and (4) "dispense as written" prescriptions.

The bill gives the Department of Consumer Protection (DCP) more oversight over sterile compounding pharmacies by, among other things, requiring them to file more reports with the department and comply with the latest pharmacopeia standards on sterile pharmaceutical preparations. It also requires sterile compounding pharmacies that provide compounded sterile products without a patient-specific prescription or medical order to obtain a DCP manufacturing license.

The bill bans the sale and delivery of counterfeit substances and grants DCP additional investigatory and enforcement authority, including the authority to impose civil penalties. The bill's definition of "counterfeit substances" mirrors the language recognized by the federal Food and Drug Administration. Existing law already prohibits selling counterfeit or misbranded drugs under the state Uniform Food, Drug, and Cosmetic Act (see BACKGROUND).

The bill broadens the categories of nonresident pharmacies that must (1) register in Connecticut, (2) comply with pharmacy reporting requirements, and (3) provide patient contact information.

Finally, the bill establishes new procedures for prescribing practitioners and pharmacists when dispensing drugs that cannot be

substituted for a generic version.

EFFECTIVE DATE: July 1, 2014

§ 2 — STERILE COMPOUNDING

The bill requires sterile compounding pharmacies to comply with (1) the latest United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding – Sterile Preparations, as amended from time to time (pharmacopeia standards) and (2) all applicable federal and state law and regulations. Such pharmacies must prepare and maintain a policy and procedure manual that complies with the pharmacopeia standards, including, among other things, information on sterilization methods and training.

Under the bill, a "sterile compounding pharmacy" is a pharmacy, including any located in healthcare institution, or a nonresident pharmacy that dispenses or compounds sterile pharmaceuticals. "Sterile pharmaceuticals" mean any drug dosage, including parenterals (medicine not administered orally), injectables, surgical irrigants and ophthalmics, devoid of viable microorganisms.

Amending Pharmacy Application

The bill requires sterile compounding pharmacies to file an addendum to their pharmacy application with DCP before compounding sterile pharmaceuticals for use in the state. The addendum must include notice that they are engaged in sterile compounding and a description of changes to the pharmacy layout. DCP, or the appropriate state oversight agency for nonresident pharmacies, must inspect the changes and DCP and the Pharmacy Commission must approve them before a pharmacy can begin compounding sterile pharmaceuticals. (It is unclear how the Pharmacy Commission or the out-of-state oversight agency will receive notice of the changes.)

With its initial nonresident pharmacy application and then every two years thereafter, the nonresident pharmacy must provide DCP with (1) proof of current inspection by its home state's regulatory

oversight agency and (2) a copy of the most recent inspection report. The inspection must be based on the latest pharmacopeia compliance standard.

Patient-Specific Requirement

The bill allows a sterile compounding pharmacy to provide patient-specific sterile pharmaceuticals only to patients, physicians, osteopaths, podiatrists, dentists, veterinarians; an acute care or long-term care hospital; or a Department of Public Health (DPH) licensed health care facility.

Manufacturing License

The bill requires sterile compounding pharmacies that provide compounded sterile products without a prescription or medical order to get a DCP manufacturing license and any required federal license or registration. A sterile compounding pharmacy may prepare and maintain on-site up to a 30-day supply of sterile pharmaceuticals. The 30 days start from the day compounding is completed, including third party analytical testing performed according to pharmacopeia standards.

Remodeling

The bill requires sterile compounding pharmacies to notify DCP at least 10 days before remodeling or relocating a pharmacy clean room; or upgrading or starting nonemergency repairs to the heating, ventilation, air conditioning, or primary engineering controls for a clean room. They must notify DCP, in writing, as soon as possible after making any emergency repair.

If the remodel, relocation, upgrade, or repair requires sterile recertification, the pharmacy must provide DCP with a copy of the recertification. An independent licensed environmental monitoring entity must perform the recertification. (The bill does not specify when the recertification is required or when DCP must receive the copy.)

Reporting Requirements

The bill requires sterile compounding pharmacies, other than those

in health care institutions, to give DCP a written report of any known violation or noncompliance with viable and nonviable environmental sampling testing, as defined by pharmacopeia standards, within one business day after discovery. A sterile compounding pharmacy within a health care facility must report the violation or noncompliance to DPH. A sampling test measures the number of particles and microorganisms in the air around the compounding area.

Under the bill, sterile compounding pharmacies must also report to DCP any administrative or legal action commenced against them by any state or federal regulatory agency or accreditation entity within five business days after becoming aware of such an action.

A physician, hospital, or health care facility that receives sterile pharmaceuticals must report to DCP any (1) dispensing errors or (2) suspected adulterated sterile pharmaceuticals. (There are no such reporting requirements for the other health professionals that may receive sterile pharmaceuticals.)

Recalls

The bill requires sterile compounding pharmacies to notify certain people when they recall sterile pharmaceuticals. By the end of the business day following the recall, they must notify (1) each patient or patient caregiver, the prescribing practitioner, and DCP when the pharmaceutical was dispensed as a patient-specific prescription or medical order and (2) each purchaser of the pharmaceutical, DCP, and the federal Food and Drug Administration (FDA) for pharmaceuticals that were not dispensed as a patient-specific prescription or medical order.

By law, the Pharmacy Commission licenses pharmacies and pharmacists. The commission may, among other administrative sanctions, refuse to authorize or renew a license or assess a maximum civil penalty of $1,000, if a pharmacy of pharmacist violates any state statute or regulation related to drugs, devices, or the practice of pharmacy (CGS § 20-579). The Pharmacy Commission is located within DCP.

§§ 7-9 — COUNTERFEIT SUBSTANCES

The bill prohibits anyone from knowingly purchasing for resale, selling, offering for sale, or delivering a counterfeit substance in any manner. Existing law already prohibits several actions related to counterfeit or misbranded drugs (see BACKGROUND).

Under the bill, a counterfeit substance is a drug or substance which, or the container or labeling of which, (1) without authorization, bears the trademark, trade name, or other identifying mark, imprint, number or device, likeness of a manufacturer, distributor, or dispenser other than the person who manufactured, distributed, or dispensed the substance and (2) falsely claims or represents the drug or substance to have been distributed by the other manufacturer, distributor, or dispenser. (It is unclear what would qualify as a "substance" or "having any likeness," since both are undefined.)

Investigatory Authority

Under the bill, DCP must investigate possible counterfeit substance violations and may hold hearings. As part of any investigation or hearing, the commissioner may administer oaths; issue subpoenas; compel testimony; and order the production of books, records, and documents. If anyone refuses to appear; testify; or to produce any book, record, or document, a Superior Court judge may issue an order compelling compliance. The hearing must be conducted in accordance to the Uniform Administrative Procedures Act.

Penalties

The DCP commissioner may take the following actions against anyone who knowingly purchases for resale, sells, offers for sale, or delivers counterfeit substances in violation of the bill's provisions:

1. suspend, revoke, refuse to renew, or place on probation a DCP license or registration;
2. assess up to a $1,000 civil penalty for each violation; and
3. issue a cease and desist order or order of restitution.

Violators may also be fined up to $10,000, imprisoned for up to one

year, or both for each violation.

Repealed Section

The bill repeals the current counterfeit substance ban, which has no penalties or enforcement procedures. The ban prohibits anyone from knowingly possessing, purchasing, trading, selling, or transferring a controlled substance that is illegally stamped or imprinted with the trademark, trade name, or other identifying mark, imprint, number, or device of a manufacturer, distributor, or dispenser other than the person who manufactured, distributed, or dispensed the substance. Under the law, controlled substances are drugs, substances, or immediate precursors in schedules I to V of the Connecticut controlled substance scheduling regulations. The term does not include alcohol, nicotine, or caffeine.

§§ 3 - 5 — NONRESIDENT PHARMACY

The bill broadens the categories of nonresident pharmacies that must (1) register in Connecticut, (2) comply with pharmacy reporting requirements, and (3) provide patient contract information. It also adds to the responsibilities of all nonresident pharmacies and to the grounds for denying, revoking, or suspending their registration.

Registration

The bill requires nonresident pharmacies that provide any aspect of the practice of pharmacy to Connecticut residents to be registered with DCP upon the Pharmacy Commission's approval. Under current law, only those that ship, mail, or deliver prescribed legend drugs or devices into the state need to register. By law, a nonresident pharmacy registration certificate fee is $750. The renewal fee is $190.

Annual Report

The bill requires registered nonresident pharmacies to:

1. Annually disclose to the Pharmacy Commission the names and titles of all pharmacists who provide any aspect of the practice of pharmacy to Connecticut residents. By law, nonresident pharmacies must also annually report the names and titles of

the principal corporate officers and pharmacists who dispense drugs or devices to Connecticut residents.

2. Comply with all lawful directions and information requests from DCP. Under current law, such pharmacies are only required to comply with requests from the commission. The bill also eliminates the requirement that pharmacies submit a statement of compliance.

3. Disclose whether they are dispensing sterile compounded products in Connecticut and submit a copy of the manufacturing license or registration issued by the appropriate state oversight agency and a copy of any FDA registration if the products are not patient-specific. (The bill does not explicitly specify to whom the disclosure is made, but presumably it is to DCP.)

4. Submit a copy of their most recent inspection report, based on pharmacopeia standards, conducted by the appropriate state oversight agency before DCP can grant a registration certificate. (It is not clear whether all states inspect based on pharmacopeia standards. Presumably under the bill, DCP may refuse to grant a registration for those that do not comply.)

5. Notify DCP within 10 days, if they have been disciplined by, or received a written advisement or warning from any federal or state regulatory agency, or any accreditation body.

6. Provide DCP with the names and addresses of all state residents to whom they delivered legend (prescription) devices or drugs within 24 hours after initiating a recall of such devices or drugs.

Penalties

The bill expands the grounds for which the Pharmacy Commission may deny, revoke, or suspend a nonresident pharmacy's registration certificate to include:

1. failing to comply with any pharmacy and dependency-

producing drug law requirements;

2. failing to comply with any federal or state law or regulation concerning drugs or the practice of pharmacy;

3. delivering into the state, adulterated or misbranded legend drugs or devices in violation of the state Uniform Food, Drug, and Cosmetic Act; or

4. any disciplinary action taken by any state or federal agency.

Current law only allows the commission to take these disciplinary actions when a nonresident pharmacy fails to comply with laws governing registration; shipping, mailing, or delivering legend devices or drugs; or advertises without a certification of registration.

The bill eliminates the commission's authority to deny, revoke, or suspend a nonresident pharmacy's registration certificate for conduct that causes serious bodily or psychological injury to a Connecticut resident. The commissioner must first refer the matter to the appropriate oversight agency in the state where the pharmacy is located.

§ 6 — DRUG MANUFACTURERS

The bill requires pharmacies that dispense compounded drugs without a prescription or an individual medical order to register in Connecticut as drug manufacturers regardless of whether their principal place of business is located in the state. By law, out-of-state manufacturers that do not compound do not need to register. The registration fee is between $285 and $940 depending on the number of pharmacists or qualified chemists the pharmacies employ.

It also specifically requires manufacturers to comply with applicable federal, state, and local statutes, regulations, and ordinances, including applicable laws concerning controlled substances and drug product salvaging or reprocessing. Current law requires wholesalers to comply with these requirements.

By law, anyone who violates the manufacturing requirements may be subject to a fine of up to $500, up to six months imprisonment, or both. In addition, the commissioner may suspend, revoke, or refuse to renew a registration, issue a reprimand letter, or place a registrant on probation, for:

1. furnishing false or fraudulent information filed with commissioner;

2. any federal or state criminal conviction concerning drugs;

3. any drug-related suspension, revocation, other restriction, or penalty issued against the registrant;

4. failing to provide adequate control against the diversion, theft, or loss of drugs; or

5. violating any federal or state drug law or regulation.

§1 — DISPENSE AS WRITTEN PRESCRIPTIONS

The bill creates new requirements for prescribing practitioners and pharmacists when dispensing drugs that cannot be substituted for a generic version.

Written Prescriptions

For written prescriptions, the bill requires the prescribing practitioner to indicate on the prescription form that the product is "brand medically necessary" or "no substitution." The bill specifies that no prescription form may default to these terms.

Telephonic Prescriptions

For telephoned prescriptions, the bill requires the pharmacist to write the phrase "brand medically necessary" or "no substitution" on the prescription or enter it in the electronic prescription record. The pharmacist must also record on the prescription (1) the time the telephone prescription was received and (2) name of the person who ordered the prescription.

Electronic Prescriptions

For electronic prescriptions, the bill requires the prescribing practitioner to select the "dispense-as-written" code. The bill specifies that no electronic prescriptions may default to "brand medically necessary" or "no substitution."

Medicaid Prescriptions

The bill eliminates the specific "Medicaid dispense as written" prescription requirements and instead requires them to conform to the bill's prescription requirements.

For Medicaid recipients, current law requires prescribing practitioners to specify the basis on which the brand name drug and dosage form is medically necessary compared to a chemically equivalent generic drug substitution. The practitioner must write, in his or her handwriting, the phrase "BRAND MEDICALLY NECESSARY," on the prescription form or on an electronically produced copy of the form. If the prescription was ordered by telephone or electronically and the form did not reproduce the practitioner's handwriting, then (1) a statement to that effect must still be on the form and (2) written certification in the practitioner's handwriting with the phrase "BRAND MEDICALLY NECESSARY" must be sent to the dispensing pharmacy within 10 days after the communication date. The phrase "BRAND MEDICALLY NECESSARY" must not be preprinted, stamped, or initialed on the form.

BACKGROUND

Prohibitions Concerning Counterfeit or Misbranded Drugs

Among other things, the state Uniform Food, Drug, and Cosmetic Act prohibits:

1. selling misbranded drugs in intrastate commerce;
2. forging or counterfeiting any mark, label, or other identification required by state or federal regulations to be on a drug;
3. placing any trademark, trade name, identifying mark, or any likeness thereof, on another drug or its container, with intent to

defraud;

4. selling, dispensing, disposing of, or concealing or keeping any drug with intent to sell, dispense, or dispose, with knowledge that a trademark, trade name, other identifying mark, or any likeness of it, has been placed on the drug in a prohibited manner; or
5. making, selling, disposing of, or keeping or concealing any printing technology or tool designed to print a trademark, trade name, other identifying mark, or any likeness of it, on any drug, with intent to defraud (CGS § 21a-93).

A violation of any of these prohibitions is generally punishable by up to six months in prison, a fine of up to $500, or both. A subsequent violation or a violation committed with intent to defraud or mislead is punishable by up to one year in prison, a fine of up to $1,000, or both (CGS § 21a-95).

Related Bill

HB 5439, reported favorably by the Human Services Committee, transfers the "Medicaid dispense as written" provisions to the Human Services statutes and imposes substantially similar prescription requirements as this bill.

COMMITTEE ACTION

General Law Committee

Joint Favorable Substitute
Yea 17 Nay 0 (03/13/2014)